

§ 285.21

determines that a need no longer exists to accredit laboratories for the services covered under the scope of the LAP. In the event that the Chief of NVLAP proposes to terminate a LAP, a notice will be published in the FEDERAL REGISTER setting forth the basis for that determination.

(b) The notice published under paragraph (a) of this section will provide a 60-day period for submitting written comments on the proposal to terminate the LAP. All written comments will be made available for public inspection and copying at the NIST Records Inspection Facility.

(c) After the comment period, the Chief of NVLAP shall determine if public support exists for the continuation of the LAP. If public comments support the continuation of the LAP, the Chief of NVLAP shall publish a FEDERAL REGISTER notice announcing the continuation of the LAP. If public support does not exist for continuation, the LAP will be terminated effective 90 days after the date of the published notice of intent to terminate the LAP.

(d) If the LAP is terminated, NVLAP shall no longer grant or renew accreditations following the effective date of termination. Accreditations previously granted will remain effective until their expiration date unless terminated voluntarily by the laboratory or revoked by NVLAP.

[49 FR 44623, Nov. 8, 1984, as amended at 55 FR 38315, Sept. 18, 1990. Redesignated and amended at 59 FR 27748, May 3, 1994; 64 FR 59617, Nov. 3, 1999]

Subpart C—Accrediting a Laboratory

§ 285.21 Applying for accreditation.

(a) A laboratory may complete and remit an application for accreditation in any of the established LAPs.

(b) Upon receipt of a laboratory's application, NVLAP shall:

- (1) Acknowledge receipt of the application;
- (2) Request further information, if necessary;
- (3) Confirm payment of fees before proceeding with the accreditation process; and
- (4) Specify the next step(s) in the accreditation process.

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(c) Accreditation of laboratories outside of the United States may require:

- (1) Translation of laboratory documentation into English; and
- (2) Payment of additional traveling expenses for on-site assessments and proficiency testing.

[49 FR 44623, Nov. 8, 1984, as amended at 55 FR 38315, Sept. 18, 1990. Redesignated and amended at 59 FR 27748, May 3, 1994]

§ 285.22 Assessing and evaluating a laboratory.

(a) Information use to evaluate a laboratory's compliance with the conditions for accreditation set out in § 285.32, the criteria for accreditation set out in § 285.33, and the technical requirements established for each LAP will include (not necessarily in this order):

- (1) Application and other material submitted by the laboratory (§ 285.32(b));
- (2) On-site assessment reports;
- (3) Laboratory performance on proficiency tests;
- (4) Laboratory responses to identified deficiencies; and
- (5) Technical evaluation.

(b) NVLAP shall arrange the assessment and evaluation of applicant laboratories in such a way as to minimize potential conflicts of interest.

(c) NVLAP shall inform each applicant laboratory of any additional action(s) that the laboratory must take to qualify for accreditation.

[59 FR 22748, May 3, 1994]

§ 285.23 Granting and renewing accreditation.

(a) NVLAP will take action to: (1) Grant initial accreditation, or (2) renew, suspend, or propose to deny or revoke accreditation of an applicant laboratory, based on the degree to which the laboratory complies with the specific NVLAP requirements.

(b) If accreditation is granted or renewed, NVLAP shall:

- (1) Provide a Certificate of Accreditation and a Scope of Accreditation to the laboratory;
- (2) Provide guidance on referencing the laboratory's accredited status, and the use of the NVLAP logo by the laboratory and its clients, as needed; and

(3) Remind the laboratory that accreditation does not relieve it from complying with applicable federal, state, and local laws and regulations.

(c) NVLAP shall notify an accredited laboratory at least 30 days before its accreditation expires advising of the action(s) the laboratory must take to renew its accreditation.

[49 FR 44623, Nov. 8, 1984, as amended at 55 FR 38315, Sept. 18, 1990. Redesignated and amended at 59 FR 27749, May 3, 1994]

§ 285.24 Denying, suspending, and revoking accreditation.

(a) If NVLAP proposes to deny or revoke accreditation of a laboratory, NVLAP shall inform the laboratory of the reasons for the proposed denial or revocation and the procedure for appealing such a decision.

(b) The laboratory will have 30 days from the date of receipt of the proposed denial or revocation letter to appeal the decision to the Director of NIST. If the laboratory appeals the decision to the Director of NIST, the proposed denial or revocation will be stayed pending the outcome of the appeal. The proposed denial or revocation will become final through the issuance of a written decision to the laboratory in the event that the laboratory does not appeal the proposed denial or revocation within that 30-day period.

(c) If NVLAP finds that an accredited laboratory has violated the terms of its accreditation or the provisions of these procedures, NVLAP may, after consultation with the laboratory, suspend the laboratory's accreditation, or advise of NVLAP's intent to revoke accreditation. If accreditation is suspended, NVLAP shall notify the laboratory of that action stating the reasons for and conditions of the suspension and specifying the action(s) the laboratory must take to have its accreditation reinstated.

(d) A laboratory whose accreditation has been denied, revoked, terminated, or expired, or which has withdrawn its application before being accredited, may reapply and be accredited if the laboratory:

(1) Completes the assessment and evaluation process; and

(2) Meets the conditions and criteria for accreditation that are set out in §§ 285.32 and 285.33.

(e) Conditions of suspension will include prohibiting the laboratory from using the NVLAP logo on its test or calibration reports during the suspension period. The determination of NVLAP whether to suspend or to propose revocation of a laboratory's accreditation will depend on the nature of the violation(s) of the terms of its accreditation.

[59 FR 22749, May 3, 1994]

§ 285.25 Voluntary termination of accreditation.

A laboratory may at any time terminate its participation and responsibilities as an accredited laboratory by advising NVLAP in writing of its desire to do so. NVLAP shall terminate the laboratory's accreditation and shall notify the laboratory stating that its accreditation has been terminated in response to its request.

[49 FR 44623, Nov. 8, 1984, as amended at 55 FR 38315, Sept. 18, 1990. Redesignated at 59 FR 22745, May 3, 1994]

§ 285.26 Change in status of laboratory.

Accreditation of a laboratory is based on specific conditions and criteria including the laboratory ownership, location, staffing, facilities, and configuration. Changes in any of these conditions or criteria could result in loss of accreditation. NVLAP must be informed if any of the conditions or criteria for accreditation are changed so that a determination can be made concerning the status of the accreditation.

[59 FR 22749, May 3, 1994]

Subpart D—Conditions and Criteria For Accreditation

§ 285.31 Application of accreditation conditions and criteria.

To become accredited and maintain accreditation, a laboratory must meet the conditions for accreditation set out in § 285.32, the criteria set out in